

REMARKS

Claims 9-16 and 21-30 are currently pending. Claims 9-16 have been withdrawn from consideration. Claims 21-30 are new and pending.

Not Fully Responsive Reply

The Reply filed on April 27, 2004 was not considered responsive to the prior Office Action, which had a mailing date of January 27, 2004, because the remarks beginning on page 6 were not of record.

Accordingly, applicants re-submit pages 6 and 7 of the Reply filed on April 27, 2004. Applicants now believe the response is fully responsive.

CONCLUSION

Applicants now believe that they have fully replied to the Office Action that was dated April 27, 2004. Accordingly, reconsideration of the rejections and allowance of the claims at an early date are earnestly solicited.

If the undersigned can be of assistance in addressing issues to advance the application to allowance, please contact the undersigned at the number set forth below.

Respectfully submitted,



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Remarks*The Claim Amendments*

Applicants have amended claims 21-23 and 25-26 to improve their form. Support for these amendments may be found throughout the specification. See, e.g., page 2, lines 17-19. Applicants have added claims 31-34. Support for added claim 31 may be found on page 15, lines 12-13. Support for added claims 32 and 34 may be found on page 13, lines 19-20. Support for added claim 33 may be found on page 17, lines 25-26. No new matter is added by the amendments. Their entry is requested.

Applicants previously canceled claims 1-8 and 17-20 and have added claims 31-34. Thus, claims 9-16 and 21-34 are pending. The Examiner has withdrawn claims 9-16 and 30 from consideration. Added claims 21-29 and 31-34 correspond to elected Group I and are subject to examination.

*The Rejection Under 35 U.S.C. §102*

The Examiner has rejected claims 21-29 under 35 U.S.C. §102(e) as being anticipated by United States published patent application US 2003/0186386 A1 (hereafter "the '386 application"). Specifically, the Examiner contends that the '386 application discloses a single linear or branched PEG molecule of molecular weight of at least 20kDal linked to the N-terminus of IL-10, citing the abstract and [0103] of the '386 application. Applicants traverse.

IL-10 is a non-covalently linked dimer comprising two subunits (polypeptide chains), each of which comprises an N-terminus. See, e.g., page 1, lines 12-13 and page 2, lines 17-19 of the specification. Claims 21-29 and 31-34 recite a pegylated IL-10 comprising one or more polyethylene glycol (PEG) molecules covalently attached via a linker to a single amino acid residue of a single subunit of IL-10. The '386 application does not teach or suggest such an IL-10/PEG conjugate. Rather, the '386 application states that "the polypeptide conjugate of the invention is one which comprises a single PEG molecule attached to the N-terminal [*sic*] of the polypeptide." See [0103] of the '386 application. Since IL-10 comprises two N-termini, pegylation of the "N-terminal" of IL-10 would produce a molecule with a PEG molecule attached to

each of the two N-terminal amino acid residues, i.e., a IL-10/PEG conjugate with pegylation on two amino acid residues, rather than the claimed mono-pegylated IL-10. For this reason alone, the '386 application does not anticipate the claimed invention.

In addition, the '386 application does not teach or suggest how to conjugate a PEG molecule to a single amino acid of the IL-10 dimer. The specification does not exemplify selectively pegylating the N-terminus of a single subunit of IL-10. Further, the sole teaching of the '386 application regarding conjugation to a single attachment group on IL-10 states that such conjugation is described in United States Patent 5,985,265. See [0099] of the '386 application. However, the instant application teaches that pegylation of IL-10 using the methods of the '265 patent "would result in its monomerization and loss of biological activity." See page 13, lines 4-6. Thus, the '386 application fails to teach how to make the claimed invention.


#### *Conclusion*

Applicants request that the Examiner allow the pending claims and pass this application to issue.

If the Examiner should have any questions regarding this response or application, he is encouraged to contact the undersigned agent.

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